REMARKS

Status of the Application

Claims 33-60, 85-91,100-103 and 114-153 are pending in the application, with claims 34, 37, 38, 41, 85-91, 100-103, 114-140 and 151-153 deemed withdrawn as directed to non-elected inventions. Claims 33, 35, 36, 39, 40, 42-60 and 141-150 were examined and stand rejected in the application. In the instant office action, the Examiner inadvertently listed the previously canceled claims 104-113 as pending.

With entry of the instant response, claims 1 and 149 are amended. Specifically, claim 149 is amended for improved clarity, i.e., by replacing "B7.1 and B7.2" with "B7.1 or B7.2." Claim 33 is amended to clarify that at least one of the MHC class II heterodimer and the accessory molecule is not naturally linked to the support of the claimed synthetic antigen presenting matrix. Explicit and implicit support for this amendment is provided throughout the specification, e.g., page 6, lines 3-7 ("synthetic antigen presenting matrix"); page 6, line 27 to page 7, line 3 (non-cellular supports or supports from a transformed cell); page 8, lines 4-6 (synthetic cell line expressing the genes not naturally present therein); and page 20, lines 28-30 (anchoring a MHC heterodimer to the support).

Applicant notes that the claim amendments presented herein do not introduce new matter. Unless otherwise indicated, the amendments have been made to improve clarity or to expedite prosecution of the subject application, and should not be construed as acquiescence of any ground of rejections.

The following remarks address issues raised in the instant Office Action.

Double Patenting

Claims 33, 35, 36, 42-60 and 141-150 were rejected on the ground of obviousness-type double patenting as being unpatentable over U.S. Patent No. 6,355,479 (the '479 patent). Applicants respectfully traverse this rejection. It is noted that claims 33-60 were restricted out by the U.S. Patent and Trademark Office from Application Serial No. 09/194,285 (the '285 application) from which the '479 patent issued. Prior to issuance of the '479 patent, these

claims were presented by Applicants in Application Serial No. 09/715,231 (the '231 application) as a divisional filing. The instant application is in turn a continuation of now abandoned '231 application. In addition, the currently rejected claims 33, 35, 36, and 42-60 are substantially identical to the claims originally presented in and restricted out from the '285 application. As such, the double patenting rejection of these claims and dependent claims 141-150 over the '479 patent which issued from the '285 application is clearly improper. See MPEP § 804.01. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, First Paragraph, Enablement

Claims 33, 35, 36, 39, 40, 42-44, 46, 48, 50, 51, 53, 54, 56, 58 and 59 were rejected as allegedly not enabled. The Examiner acknowledges that the specification enables accessory molecules selected from the costimulatory molecules B7.1 and B7.2, the adhesion molecules ICAM-1, iCAM-2, ICAM-3, LFA-1 and LFA-3, and the survival molecules Fas ligand, TNF receptor and CD70. However, the Examiner takes the view that the claims are not enabled to the extent that the claims may encompass other accessory molecules that are not specifically exemplified or taught in the specification. This rejection is respectfully traversed for the reasons stated below.

As the Examiner correctly noted, "[t]he test of enablement is whether one reasonaly skilled in the art could make and use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8USPQ2d 1217, 1223 (Fed. Cir. 1988). See also, In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir, 1988). Also, enablement is not precluded even if some experimentation is necessary. *Atlas Powder Co. v. E. I. duPont de Nemours & Co.*, 224 USPQ 409, 413 (Fed. Cir. 1984).

In addition, it is well established that what is exemplified in a specification should not be equated with its teachings, and that an applicant should not be limited to the specific embodiments exemplified in the specification when other operable embodiments may be discovered with only routine experimentation using the teaching of the specification. See, e.g., *In re Goffe*, 191 USPQ 429, 431 (CCPA 1976) ["To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified

for 'preferred' materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts"]. See also, *In re Anderson*, 176 USPQ 331, 333 (CCPA 1973) ["what the Patent Office is here attempting is to limit the claims to the specific examples, notwithstanding the disclosure of a broader invention. This it may not do"].

Furthermore, in order to make a rejection under the enablement requirement, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure).

As detailed below, applying these legal standards to the instant case, it is readily apparent that no undue experimentation would be required to make and use the claimed invention with respect to other accessory molecules that can be employed in the present invention. In addition, the instant office action did not establish a reasonable basis for a prima facie case of lack of enablement. Rather, with due respect, Applicants note that the office action set forth no sound and scientifically based reasoning as to why the skilled artisan would not be able to employ other accessory molecules in the present invention.

First, the teachings of the specification enable the scope of the claimed invention as evidenced by the state of the art, the teachings of the specification, and the nature of the claimed invention. The presently claimed invention relates to a synthetic antigen presenting matrix for activating CD4+ T-cells. The claimed matrix comprises a support for operably linking the extracellular portion of a MHC class II heterodimer and the extracellular portion of an accessory molecule. As taught in the specification (e.g., page 8, lines 4-18 and 21-26), the invention is predicated on the unexpected activities brought about by the combination of these recited claim elements, e.g., selective activation of CD4+ T cells in a reproducible and predictable manner. Patentability of the invention resides on such combination and the demonstrated activities.

In other words, the invention is not directed to accessory molecules per se. The exact nature of the accessory molecule to be used does not underline the inventive feature of the claimed invention. Since the claimed invention is predicated on the novel and generic concept

of the recited combination, the claims should not be limited to the specific accessory molecules disclosed in the specification. Otherwise, as the specific accessory molecule to be used is not essential to the practice of the present invention, one could easily circumvent any claims so limited by employing an accessory molecule that was not specifically described in the present invention. As the Examiner can readily appreciate, such limited claims would have very little practical value and would also not reflect the broad and generic nature of Applicants' contribution to the art.

In addition, teachings or enabling disclosure provided by the subject specification are not limited to the specific accessory molecules described in the specification. Instead, a high level of guidance and working examples are provided in the specification so that one would readily be able to practice the claimed invention with other accessory molecules. The specification provides detailed teachings for the production and use of accessory molecules in the context of the present invention. For example, in addition to the specific accessory molecules noted in the office action, the specification also teaches the use of a number of accessory molecules in the practice of the claimed invention and provides experimental data on specific accessory molecules in the practice of the claimed invention. Indeed, although no working examples are required to demonstrate that an invention is enabled (see MPEP § 2164.02), the specification has provided working examples to show how to make and use two different accessory molecules in the practice of the claimed invention. At pages 75-76 and 84 of the specification, the specification teaches the use of B7.1 and B7.2 accessory molecules in the practice of the claimed invention. These exemplified embodiments demonstrated the actual reduction to practice of the claimed invention.

Further, many accessory molecules that can be employed in the invention are all well known at the time the application was filed. The role of accessory molecules in the MHC antigen presentation pathway was well understood, and the use of accessory molecules was highly predictable in the art of MHC immunology. This is evident from Janeway et al. (Immunobiology 1997 Garland Press NY, pages 7.7, 7.8, and 7.25) which was cited by the Examiner in the related co-pending application serial no. 10/903,213 as evidence of the state of the art. These factors, coupled with the teachings of the specification showing the production and use of accessory molecules in insect synthetic antigen presenting cells, would reasonably

indicate that no undue experimentation would be required to employ other accessory molecules in the practice of the invention. There can be little doubt that the teachings of the specification and knowledge well known in the art provide sufficient enablement of the genus of accessory molecules in the claimed invention.

For all the reasons stated above, Applicants submit the presently claimed invention is enabled and request that the present rejection be withdrawn.

Rejection under 35 USC §112, Second Paragraph

Claim 149 was rejected as allegedly being indefinite in the recitation of "the at least one accessory molecule is B7.1 and B7.2." In response, Applicants have herein amended the claim which now recites "the at least one accessory molecule is B7.1 or B7.2." Applicants believe the amendment has made the claim language abundantly clear. Withdrawal of the instant rejection is accordingly requested.

Rejection under 35 U.S.C. § 102(b)

Claims 33, 35, 36, 42, 44-60 and 141-150 were further rejected as allegedly anticipated by Banula et al. (Immunol. 79-298-304, 1993). The Examiner notes that Banuls et al. discusses naturally existing antigen presenting matrix represented by rat dendritic cells. The Examiner acknowledges that the present claims recite a synthetic antigen presenting matrix which comprises an extracellular portion of a recombinant MHC class II heterodimer. However, the Examiner asserts that neither the term "synthetic" in the preamble of the claims nor the word "recombinant" recited in the claim body provides any structural property of the claimed matrix that distinguish them over a naturally existing antigen presenting molecule.

Applicants do not agree with the reasoning underlying the instant rejection. Nonetheless, in an effort to solely advance prosecution of the subject patent application, Applicants have amended the claims which now specify that the at least one of the MHC class II heterodimer and the accessory molecule is not naturally linked to the support. This amendment makes it abundantly clear that the claimed invention does not encompass a naturally existing antigen presenting cell or matrix. Therefore, the instant rejection should be withdrawn.

CONCLUSION

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If a telephone conference would expedite prosecution of this application, please telephone the undersigned attorney at 858-784-2937. If there are any additional fees (or overpayments) associated with this Response, or any Response associated with this application, the Director is hereby authorized to charge (or credit) our Deposit Account No. 19-0962.

Respectfully submitted,

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Date Hugh Wang, Ph.D., Reg. No 47,163

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